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10/684,124	10/10/2003	Fred H. Burbank	R0367-01002	2747

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EXAMINER	
RALIS, STEPHEN J	
ART UNIT	**PAPER NUMBER**
3742	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	**Application No.** 10/684,124	**Applicant(s)** BURBANK ET AL.
	Examiner Stephen J. Ralis	**Art Unit** 3742

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 & 30 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,35-38 and 44-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,35-38 and 44-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application (PTO-152)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/14/2006*.	6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 09 March 2006, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. copending Patent Application No. 10,719,448 (now U.S. Patent No. 6,996,433), has been approved and entered. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

   1. Determining the scope and contents of the prior art.
   2. Ascertaining the differences between the prior art and the claims at issue.
   3. Resolving the level of ordinary skill in the pertinent art.
   4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter (U.S. Patent No. 4,863,470) or Sinaiko (U.S. Patent No. 3,341,417), Fulton, III et al.

(U.S. Patent No. 6,270,464), and further in view of Foerster et al. (U.S. Patent No. 6,228,055).

Carter discloses an X-ray detectable body 16 embedded in gelatin body 14 (column 2, lines 32-33, 47- 48 and 59-63; see Figures 1, 2). Also, Sinaiko discloses an X-ray detectable body embedded in a gelatin body (see (1) column 2, lines 30-37 and 59-62, (2) column 3, lines 53-65, and (3) column 3, line 74 - column 4, line 28.

The claim differs from the previously cited prior art in calling for the gelatin to be dehydrated and configured for delivery to a biopsy site through a delivery cannula. But forming biopsy site markers from dehydrated materials, including gelatins, is well known in the art. Fulton, III et al., for example, forms a biopsy site marker 34 from a dehydrated collagen so that the marker swells and softens in its post-delivery state following delivery from delivery device 32 (see (1) column 5, lines 3-21, (2) column 6, lines 47-50, and (3) Figure 5). The marker is ultrasonically detectable (column 3, lines 58-59). Furthermore, Fulton, III et al. note in column 6, lines 57-63 that a gelatin (line 63) may be substituted for the collagen material. In view of Fulton, III et al., it would have been obvious to one of ordinary skill in the ad at the time of the invention to provide a dehydrated gelatin in the previously-described X-ray detectable bodies so that that the body swells and softens in its post-delivery state. Such a feature conserves space during storage in view of the marker's smaller size prior to implantation and subsequent swelling. Regarding the limitation in the preamble that the marker is "storable", the markers of the prior art are inherently storable.

The claim also differs from the previously cited prior ad in calling for a plurality of separate ultrasonically-detectable bodies. Delivering a plurality of detectable bodies via a cannula (tube 54, column 4, lines 31-35), however, is well known in the art. Foerster et al., for example, disclose in Figures 12-15 a cannula (tube 54) that is adapted to eject a plurality of biopsy markers (12b-12e) to a desired biopsy site via an ejector rod (column 10, lines 5-11). Such an arrangement enables implanting an array of markers with a single cannula without reloading, thus enabling implantation at multiple biopsy sites (column 11, lines 8-15). In view of Foerster et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus to enable implanting of an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites.

4. Claims 35-38, 50-52, 55 and 59-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, III et al. (U.S. Patent No. 6,270,464) in view of Yamamoto (U.S. Patent No. 4,847,049) and further in view of Foerster et al. (U.S. Patent No. 6,228,055).

Fulton, III et al. disclose a biopsy site marker 34 from a dehydrated collagen so that the marker swells and softens in its post-delivery state following delivery from delivery device 32 (see (1) column 5, lines 3-21, (2) column 6, lines 47-50, and (3) Figure 5). In addition to its visual detectability via a coloring agent (column 3, lines 53-54), the marker is also ultrasonically and radiographically detectable (column 3, lines

56-59). Furthermore, Fulton, III et al. note in column 6, lines 57-63 that a gelatin (line 63) may be substituted for the collagen material.

The claims differ from Fulton, III et al. (US 6,270,464) in calling for a radiographically detectable metallic ion bound to the bioabsorbable material. But binding metallic ions to collagens in medical devices used in contact with bodily fluids and tissues is well known in the art to protect against bacterial and fungal attack. Yamamoto, for example, discloses contacting a renatured, cross-linked collagen with silver ion-containing solution with a PH from 4.0-9.0 to cause silver ions to be chelated to functional groups in the renatured collagen. The silver-chelated collagen is then exposed to UV radiation at a 210-310 nm wavelength for 5-15 minutes (column 4, lines 23-24) to strengthen the binding of the silver ions to the renatured collagen (column 2, lines 7-19 and 60-68). In view of Yamamoto (US 4,847,049), it would have been obvious to one of ordinary skill in the art at the time of the invention to bind a radiographically detectable metallic ion to the bioabsorbable material of Fulton, III et al. to cause silver ions to be chelated to functional groups in the collagen, thus further protecting against bacterial and fungal attack.

The claims also differ from the previously cited prior art in calling for a plurality of separate ultrasonically-detectable and radiographically-detectable bodies. Delivering a plurality of detectable bodies via a cannula (tube 54, column 4, lines 31-35), however, is well known in the art. Foerster et al., for example, disclose in Figures 12-15 a cannula (tube 54) that is adapted to eject a plurality of biopsy markers (12b-12e) to a desired biopsy site via an ejector rod (column 10, lines 5-11). Foerster et al. also disclose the use of a gamma-shaped radiopaque element having a pair of extensions with free-ends to outwardly extend, thereby sufficiently to anchoring themselves to the target tissue (column 11, lines 27-32; see Figures 12-14). Such an arrangement enables implanting an array of markers with a single cannula without reloading, thus enabling implantation at multiple biopsy sites (column 11, lines 8-15). In view of Foerster et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus to enable secure implanting of an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites.

Regarding claims 35, 50 and 59, the cited prior art does not expressly disclose the body's ability to remain solid at 40° C. However, not only is such a feature implied by the prior art to ensure the marker remained intact after implantation (i.e., upon exposure to body temperature), the skilled artisan would know to select such a body because the marker is intended to be implanted into the patient and therefore must remain solid at temperatures several degrees above body temperature. Therefore, it would have been obvious to one of ordinary skill in the art to provide a body that is solid at 40° C in the previously described apparatus to ensure the marker remained intact after implantation.

5. Claims 44, 53, 54 and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, III et al. (U.S. Patent No. 6,270,464) in view of Foerster et al. (U.S. Patent No. 6,228,055).

The claims differ from the previously cited prior art in calling for a delivery cannula with inner lumen and plunger to press against the marker bodies to discharge them from the cannula's discharge port. But delivery cannulas with such features are well known in the art. Foerster et al., for example, disclose in Figures 12-15 a delivery cannula for implanting biopsy site markers that ejects biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window. Such a feature utilizes compressive forces rather than tensile forces for delivery (column 10, lines 5-12). Moreover, as noted in column 10, lines 5-11, the device can eject multiple markers individually in series. In view of Foerster et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a marker delivery cannula and plunger in lieu of the marker delivery device of Fulton, III et al. to eject biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window, thus eliminating a procedural step and saving time.

The claims also differ from Fulton, III et al. in calling for a plurality of separate ultrasonically-detectable bodies and radiographically-detectable bodies. Delivering a plurality of detectable bodies via a cannula (tube 54, column 4, lines 31-35), however, is well known in the art. Foerster et al., for example, disclose in Figures 12-15 a cannula (tube 54) that is adapted to eject a plurality of biopsy markers (12b-12e) to a desired biopsy site via an ejector rod (column 10, lines 5-11). Foerster et al. also disclose the use of a gamma-shaped radiopaque element having a pair of extensions with free-ends to outwardly extend, thereby sufficiently to anchoring themselves to the target tissue (column 11, lines 27-32; see Figures 12-14). Such an arrangement enables implanting an array of markers with a single cannula without reloading, thus enabling implantation at multiple biopsy sites (column 11, lines 8-15). In view of Foerster et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus to enable secure implanting of an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites.

Regarding claim 56, the cited prior art does not expressly disclose the body's ability to remain solid at 40° C. However, not only is such a feature implied by the prior art to ensure the marker remained intact after implantation (i.e., upon exposure to body temperature), the skilled artisan would know to select such a body because the marker is intended to be implanted into the patient and therefore must remain solid at temperatures several degrees above body temperature. Therefore, it would have been obvious to one of ordinary skill in the art to provide a body that is solid at 40° C in the previously described apparatus to ensure the marker remained intact after implantation.

6. Claims 45-49 rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, III et al. (U.S. Patent No. 6,270,464) in view of Yamamoto (U.S. Patent No. 4,847,049) and further in view of Foerster et al. (U.S. Patent No. 6,228,055).

The claims differ from the previously cited prior ad in calling for a delivery cannula with inner lumen and plunger to press against the marker bodies to discharge them from the cannula's discharge port. . But delivery cannulas with such features are well known in the art. Foerster et al., for example, disclose in Figures 12-15 a delivery cannula for implanting biopsy site markers that ejects biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window. Such a feature utilizes compressive forces rather than tensile forces for delivery (column 10, lines 5-12). Moreover, as noted in column 10, lines 5-11, the device can eject multiple markers individually in series. In view of Foerster et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a marker delivery cannula and plunger in lieu of the marker delivery device of Fulton, III et al. to eject biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window, thus eliminating a procedural step and saving time.

The claims differ from the previously cited prior ad in calling for a plurality of separate ultrasonically-detectable bodies. a cannula, however, is well known in the art. Delivering a plurality of detectable bodies via a cannula (tube 54, column 4, lines 31-35), however, is well known in the art. Foerster et al., for example, disclose in Figures 12-15 a cannula (tube 54) that is adapted to eject a plurality of biopsy markers (12b-12e) to a desired biopsy site via an ejector rod (column 10, lines 5-11). Foerster et al. also disclose the use of a gamma-shaped radiopaque element having a pair of extensions with free-ends to outwardly extend, thereby sufficiently to anchoring themselves to the target tissue (column 11, lines 27-32; see Figures 12-14). Such an arrangement enables implanting an array of markers with a single cannula without reloading, thus enabling implantation at multiple biopsy sites (column 11, lines 8-15). In view of Foerster et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus to enable secure implanting of an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites.

Regarding claims 46-49, although the cited prior ad does not disclose the specific Bloom rating of the body, the body of the cited prior art is nonetheless within the claimed Bloom rating range to achieve implantation (i.e., the body must possess the requisite degree of softness, but also a certain amount of firmness to facilitate implantation).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen J. Ralis whose telephone number is 571-272-6227. The examiner can normally be reached on Monday - Friday, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans can be reached on 571-272-4777. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stephen J Ralis
Examiner
Art Unit 3742

SJR
June 12, 2006

Robin O. Evans
ROBIN O. EVANS
PRIMARY EXAMINER
6/12/06